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BHAT, N EXAMINER

ART UNIT	PAPER NUMBER
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1312

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DATE MAILED:

08/01/96

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

## Office Action Summary

Application No.  
08/548,048

Applicant(s)

Carson et al.

Examiner

N. Bhat

Group Art Unit

1312

 Responsive to communication(s) filed on May 17, 1996 This action is FINAL. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

 Claim(s) 25-41 is/are pending in the application.Of the above, claim(s) 25-28 is/are withdrawn from consideration. Claim(s) \_\_\_\_\_ is/are allowed. Claim(s) 29-41 is/are rejected. Claim(s) \_\_\_\_\_ is/are objected to. Claims 25-41 are subject to restriction or election requirement.

### Application Papers

 See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner. The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved. The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

 Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). All  Some\*  None of the CERTIFIED copies of the priority documents have been received. received in Application No. (Series Code/Serial Number) \_\_\_\_\_. received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

 Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

 Notice of References Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s). 2 Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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**DETAILED ACTION**

1. Claims 25-28 have been withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a non-elected method of making the exchanger. Election was made **without** traverse in Paper No. 7. The restriction requirement is hereby made **FINAL**. Action on the merits of Group II, the exchanger, claims 29-41 follows:
2. Claims 33 and 37-41 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 33, applicant claims "...wherein the cap engages the central core in a pres-fit manner." Applicant is suggested to recite "...wherein the cap engages the central core in a press-fitting relationship.". The recitation phrased in as suggested is more positive and specifically recites the cooperative relationship between the elements. This is merely a suggestion. Applicant is **not** required to make the change. In claim 37, applicant recites "...the exchanger is adaptable to being manufacture in a plurality of different capacities by pre-determining the outer casing...", this recitation is not a positive, meaningful limitation which describes the apparatus but instead describes how the apparatus is made. Therefore, a patent which includes all of applicant's structural elements would meet

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applicant's apparatus claim even though applicant has described a manufacturing proviso. Applicant should draft the claims which positively recite all essential elements necessary to the exchanger and the structural relationship between said essential elements avoiding how the apparatus is manufactured. Appropriate correction is required.

3. Claims 38-41 are rejected as being dependent upon a rejected base claim.

4. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 86 S.Ct. 684, 15 L.Ed. 2nd 545 (1966), 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103 are summarized as follows:

1. Determining the scope and contents of the prior art;

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2. Ascertaining the differences between the prior art and the claims at issue; and
3. Resolving the level of ordinary skill in the pertinent art.

6. Claims 29-41 are rejected under 35 U.S.C. § 103 as being unpatentable over Jones et al. [US Patent 5,124,127]

Jones et al. teach an oxygenator which includes a top cap (32), and outer casing cap (52), and enclosed fiber bundle unit (54), and enclosed heat exchanger unit (56), and bottom cap (40). From figure 5, there is shown a tapered central core (58) having a generally tube but tapered exterior shape such that its top end (60) is larger than its bottom end (62). The tapered central core (58) has a frusto-conical shape, the taper on the central core is about 2°. The fiber bundle (22) is wound onto the tapered core (58) with a substantially uniform thickness such that the circular periphery of the fiber bundle (22) has substantially the same amount of taper as the central core (58). The central core (58) and fiber bundle (22) are then enclosed or encased by interior housing (20). The interior housing (20) has a frusto-conical shape comprising a tubular, tapered housing with a length substantially equal to the length of the central core (58). A flange of top (76) extends radially outward from the interior housing (20), the flange (78) has a generally "L-shaped" cross-section which extends outward and upward from the interior housing (20). An O-ring (79) is located in a recess or groove (not shown) on the upward extending portion of the L-

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shaped flange (78). the flange (78) thus acts as a spring to resiliently urge the O-ring (79) outwardly against any radially compressive force or contacting structure. The diameter of the interior housing (20) is positioned concentrically with the central core (58), with the corresponding ends being radially aligned, the interior housing (20) is slightly smaller in diameter than the corresponding on the outside of the fiber bundle(22). Thus the interior housing or casing (20) slides over the core (58) and fiber bundle (22) such that the ends of the casing are positioned radially outward of the ends (60,62) of the central core (58) providing a slight radial compression of the fiber bundle and a close fit with the casing. [Note column 7, lines 10-25 and Column 8, lines 9-47]

However, Jones et al. does not specifically teach an angled flange.

It would have been obvious from reading Jones et al. to provide an exchanger having an outer casing having a tubular outer wall and an angle d flange connected to and extending from the outer casing, wherein the flange has a generally L-shaped cross-section and including a wall extending substantially parallel to the outer wall of the casing and being circumferentially spaced therefrom and at least one cap located on the end of the outer casing cap having a wall extending substantially parallel to the outer wall of the casing and being

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circumferentially spaced therefrom and a circumferential groove located in an edge of the cap wall for receiving the distal end of the flange wall.

As stated above, Jones et al. describes the invention substantially as claimed. Jones et al. teach an outer casing, a flange having a generally L-shaped cross-section, which is connected to the casing and at least one cap located on an end of the outer casing. Specifically, Jones et al. teach that the cap (52) has a downwardly depending flange (109) which forms a circular hole or aperture (108) in the center of the cap (52). The flange (109) is substantially cylindrical shape having a diameter approximating that of the L-shaped flange (78) on the interior of the housing. [Note Figure 3, and Column 11, 56-68 and Column 12, lines 1-4] Further, taught in Jones et al. is that the outer casing and the central core has a taper of at least 2°. Jones et al. teach specially that too great of taper angle on the parts will limit the amount of adjustability and tolerance variation and axial motion of the respective part [Note Column 16, lines 43-68] which provides at least a suggestion that the flange used in the Jones et al. may be angled inherently as there is a taper of the central core and casing assembly or alternatively, that providing an angled flange in the exchanger assembly would have been obvious to one having ordinary skill in the art in

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assembling and manufacturing of exchanger particularly blood oxygenators absent criticality in showing.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lewin teach a blood oxygenator with integral heat exchanger.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina Bhat whose telephone number is (703) 308-3879. The examiner can normally be reached on Mondays- Fridays from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, R. Warden, can be reached on (703) 308-2920. The fax phone number for this Group is (703) 305-7719.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0651.

N. Bhat

*NBhat*  
NINA BHAT  
PRIMARY EXAMINER  
GROUP 1300